510(k) Summary

FEB 2 2 2013

Manufacturer: Cothera
5796 Armada Drive
Ste. 250
Carlsbad, CA 92008

Date Prepared: January 30, 2013

Device Trade Name: VPULSE

Contact: Justin Eggleton
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Classification: 21 CFR §870.5800

Class: II

Product Code: JOW

Indications and Contraindications for Use:
The VPULSE is intended to function as an intermittent, external compression device in extremities to prevent and reduce complications of poor circulation. This includes:

- deep vein thrombosis,
- chronic venous insufficiency,
- venous stasis ulcers,
- post-mastectomy edema and chronic lymphedema,
- reduction of edema associated with soft tissue injuries such as burns, postoperative edema, and ligament sprains,
- localized cold thermal therapy for post-traumatic and post-surgical medical and/or surgical conditions)
- Aids the blood flow back to the heart
- Treat and assist healing of cutaneous ulceration (wounds), reduce wound healing time, enhance arterial circulation (blood flow), reduce compartmental pressures, reduce edema (swelling), reduce the need for anticoagulant (blood thinning) medications.

For Controlled Cold Therapy:

Contraindications
Patients should be aware of situations where cold therapy may not be appropriate, detrimental to a specific condition or otherwise contraindicated for use: Patients with specific cold sensitivity symptoms, such

as:

- Diabetes
- Cold uticaria
- Cryoglobulinemia
- Raynaud's syndrome
- Proximal cold hemoglobinuria
- Vasospastic disease
- Cold hypersensitivity
- Compromised local circulation

Patients should take caution in applying cold therapy over open sores and abrasions. At a minimum, these areas should be cleaned and bandaged.

When using the VPULSE, periodically check the skin where the pad is applied. Discontinue use if continued numbness, skin discoloration, blisters, etc. are present. Please refer to your healthcare professional prior to applying this system and / or using the system for extended periods of time.

For Dynamic Compression Therapy and Sequential Compression Therapy:

Contraindications

Patients with the following conditions should not use the VPULSE:

- Presumptive evidence of congestive heart failure
- Suspected/observed pre-existing deep vein thrombosis or pulmonary embolism
- Suspected/observed deep acute venal thrombosis (phlebothrombosis)
- Suspected/observed inflammatory phlebitis process
- Suspected/observed pulmonary edema
- Suspected /observed pulmonary embolism
- Suspected/observed acute inflammations of the veins (thrombophlebitis)
- Suspected/observed decompensated cardiac insufficiency
- Suspected/observed arterial dysregulation
- Suspected/observed erysipelas
- Suspected/observed carcinoma and carcinoma metastasis in the affected extremity
- Suspected/observed decompensated hypertonia
- Suspected/observed acute inflammatory skin diseases or infection
- Suspected/observed venous or arterial occlusive disease
- Determined venous and lymphatic return is undesirable
- Suspected/observed patient has Raynaud's Disease

- Suspected/observed poor peripheral circulation
- Suspected/observed hypersensitivity to cold
- Medical situations where increased venous and lymphatic return is undesirable
- Leg gangrene
- Recent skin graft
- Patient therapy contact on extremity containing a fracture; or
- Extremities that are not sensitive to pain

Use with Caution and under direct supervision of a physician

- Extremities not sensitive to pain
- Individuals with extremely low blood pressure
- Individuals with Raynaud's Disease
- Hypersensitivity to cold
- Children
- Diabetics

Device Description:
The VPULSE system is a device designed to function as a dual intermittent external pneumatic compression device. The intended therapies of the device are dynamic pneumatic compression therapy (DCT) in order to aid in the reduction and control of edema including lymphedema of the upper and lower extremities and venous stasis ulcers, and intermittent sequential pneumatic compression (SCT) in order to reduce the risk of the formation and prevent the occurrence of a pulmonary embolism resulting from a deep vein thrombosis (DVT) – collectively referred to as venous thromboembolism (VTE) - by aiding in the blood flow back to the heart via lower extremity limb compression.

The VPULSE system consists of a control unit, tubing set and a family of single-patient applied wraps.

The control unit contains a pneumatic pump and air reservoir for inflation of the DCT an SCT wraps, a fluid pump and user filled fluid canister for water circulation into the DCT wrap, and supporting controls to deliver and monitor the modalities. The control unit allows the patient to select and apply the treatment functions concurrently or individually.

The tubing set allows the patient to connect the wraps to the control unit and is of a length that allows treatment to be applied in a physical position comfortable for the user.

There are two (2) types of wraps given the intended treatment function of DCT and/or SCT. The DCT wraps are typically applied to an acute injury site usually the result of surgery. The SCT wraps are typically applied to the calves.

Predicate Device(s):
Predicate devices cited include the Thermotek NanoTherm™ and VascuTherm™ (K061866).

	Subject Device	**Predicate Devices**
Manufacturer	Cothera	Thermotek
Trade Name	VPulse	NanoTherm, VascuTherm

	Subject Device	Predicate Devices
510(k) Number	(Subject Device)	K061866
Product Code Regulation Number	JOW (21 CFR §870.5800)	JOW (21 CFR §870.5800)
Intended Use	The VPULSE is intended to function as an intermittent, external compression device in extremities to prevent and reduce complications of poor circulation. This includes: • deep vein thrombosis, • chronic venous insufficiency, • venous stasis ulcers, • post-mastectomy edema and chronic lymphedema, • reduction of edema associated with soft tissue injuries such as burns, postoperative edema, and ligament sprains, • localized thermal therapy (hot or cold) for post-traumatic and post-surgical medical and/or surgical conditions) • Aids the blood flow back to the heart • Treat and assist healing of cutaneous ulceration (wounds), reduce wound healing time, enhance arterial circulation (blood flow), reduce compartmental pressures, reduce edema (swelling), reduce the need for anticoagulant (blood thinning) medications.	The NanoTherm and VascuTherm systems are devices that are intended to function as intermittent, external pneumatic compression devices. The intended therapy of the NanoTherm device is to aid in the reduction and control of edema including lymphedema of the upper and lower extremities and venous stasis ulcers. The intended therapy of the VascuTherm device is to reduce the risk of the formation of deep venous thrombosis (DVT) by aiding in blood flow back to the heart via lower extremity limb compression in addition to the intended uses of the NanoTherm device.
Cycle Time	80 seconds	60 seconds
Inflation Time	10 seconds (Sequential Compression)	30 seconds (DVT) 20 seconds (Edema/Lymphedema Therapy)
Deflation Time	70 seconds (Sequential Compression)	30 seconds (DVT) 40 seconds (Edema/Lymphedema Therapy)
Pump Pressure Range	2-60 mm Hg +/- 20% (DVT) 2-50 mm Hg (Dynamic Compression – Edema/Lymphedema Therapy)	45-100 mm Hg +/- 5 mm Hg (DVT) 30 mm Hg +/- 5 mm Hg (Edema/Lymphedema Therapy)
Default Pressure	60 mm Hg (DVT, Calf) 50 mm Hg (Edema/Lymphedema Therapy)	45 mm Hg (DVT, Calf) 30 mm Hg (Edema/Lymphedema Therapy)
Therapy Temperature Range	Cold: 41F minimum, 80F maximum	Heat: 105F Cold: 43F to 49F
Sterility (Wrap)	Non-Sterile	Non-Sterile
Biocompatibility	ISO 10993-1, 5, 10	ISO 10993-1
Single Patient Use (Wrap)	Yes	Yes
Safety	IEC 60601-1 (General Requirements for Medical Electrical Equipment)	IEC 60601-1 (General Requirements for Medical Electrical Equipment)

	Subject Device	Predicate Devices
	IEC 60101-1-2 (Medical Electrical Equipment: Collateral Standard)	IEC 60601-1-1 (Emissions, Class A) IEC 60601-1-2 (Immunity)

Performance:
To demonstrate the performance of the Cothera VPULSE, bladder fatigue, static burst pressure, thermal, biocompatiblility, and inflation/deflation curve analysis were performed. In addition, adherence to applicable medical electrical equipment safety standards was demonstrated.

Conclusion:
The Cothera VPULSE has been shown to be substantially equivalent to predicates in the above described indications, performance parameters, and safety parameters.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

February 22, 2013

Cothera, LLC
c/o Mr. Justin Eggleton
Musculoskeletal Clinical Regulatory Advisers, LLC
1331 H Street NW, 12th Floor
Washington, DC 20005

Re: K122640
Trade/Device Name: VPULSE
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: January 30, 2013
Received: January 31, 2013

Dear Mr. Eggleton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Matthew G. Hillebrenner

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): ___K122640_____

Device Name: Cothera VPULSE

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- chronic venous insufficiency,
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- post-mastectomy edema and chronic lymphedema,
- reduction of edema associated with soft tissue injuries such as burns, postoperative edema, and ligament sprains,
- localized cold thermal therapy for post-traumatic and post-surgical medical and/or surgical conditions)
- Aids the blood flow back to the heart
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Prescription Use ___√____ (Part 29 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (29 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Matthew G. Hillebrenner